

Appl. No. : 10/055,875  
Filed : January 21, 2002

### SUMMARY OF INTERVIEW

Date, Type

August 2, 2004; Telephonic

In Attendance

Exr. Roy Punnoose; James R. Braig; William B. Bunker, Reg. No. 29,365; Mark J. Kertz, Reg. No. 43,711.

Exhibits and/or Demonstrations

None.

Identification of Claims Discussed

Discussed possible amendments to Claim 1.

Identification of Prior Art Discussed

Neufeld US 4,569,589; Poto US 5,795,543

Principal Arguments and Other Matters

Neufeld failed to teach or suggest proposed amendments to Claim 1; no suggestion of a disposable sample element or patient-operable or patient-usable components.

Results of Interview

No agreement was reached as to patentability.

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### REMARKS

In response to the Office Action mailed on July 1, 2004, Applicant respectfully requests the Examiner to reconsider the above-captioned patent application in view of the foregoing amendments and the following comments. As a result of the amendments listed above, Claims 95-113 remain pending. Claims 1-13, 15-19, 21-42, 62-70 and 72-76 have been cancelled without prejudice or disclaimer, and new Claims 95-113 have been added.

In the Office Action, the Examiner rejected the claims as follows:

CLAIM NOS.	REJECTION		
	BASIS	PRIMARY REFERENCE	SECONDARY REFERENCE(S)
1, 5, 62, 70	102(b)	Neufeld US 4,569,589	n/a
16-19, 73-76	103(a)	Neufeld US 4,569,589	n/a
2-4, 6-13, 35-36, 63-64	103(a)	Neufeld US 4,569,589	Poto US 5,795,543
15, 21-25	103(a)	Neufeld US 4,569,589	Poto US 5,795,543 Fodgaard 5,817,007
26-34, 37-42	103(a)	Neufeld US 4,569,589	Poto US 5,795,543 Fodgaard 5,817,007 Clift 5,452,716

### Telephonic Interview

The undersigned Attorney thanks Examiner Roy Punnoose for the courteous telephonic interview of August 2, 2004, summarized above.

### Rejected Claims

Claims 1-13, 15-19, 21-42, 62-70 and 72-76 stand rejected as being unpatentable over the prior art of record. Applicant has cancelled these claims without prejudice or disclaimer, thereby mooted the Examiner's rejections. Nonetheless Applicant respectfully does not concede the correctness of the Examiner's rejections, and has cancelled Claims 1-13, 15-19, 21-42, 62-70 and

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72-76 only to expedite prosecution of the present application. Applicant reserves the right to pursue similar claims in a continuation or other descendent of the present application.

#### New Claims

Applicant submits herein new Claims 95-113 which are believed to be allowable over the prior art of record. For example, the Neufeld patent, cited in the rejection of the previous independent claims, fails to teach or suggest new independent Claim 95, which recites:

95. (NEW) A method for determining the concentration of an analyte in a patient, in no particular sequence, comprising:

providing an optical detection system which is portable and sized and configured to be small enough to fit in the palm or pocket of the patient, the detection system comprising a housing, at least one source of electromagnetic radiation, at least one detector, an optical path extending between the source and the detector, and a filtering system in the optical path, the filtering system configured to allow passage of at least one of the following wavelengths emitted by the source: about 4.2  $\mu\text{m}$ , about 5.25  $\mu\text{m}$ , about 6.12  $\mu\text{m}$ , about 7.4  $\mu\text{m}$ , about 8.0  $\mu\text{m}$ , about 8.45  $\mu\text{m}$ , about 9.25  $\mu\text{m}$ , about 9.65  $\mu\text{m}$ , about 10.4  $\mu\text{m}$ , about 12.2  $\mu\text{m}$ ;

providing a disposable sample element comprising a reagentless sample cell and an opening, the sample cell and the opening being in fluid communication through a sample supply passage, the sample cell being formed at least in part by at least one window constructed from a material selected from the group consisting of polyethylene and polypropylene;

installing the sample element into the housing of the optical detection system;

positioning the sample element such that the sample cell is located at least partially in the optical path and such that the opening of the sample element is exposed outside the housing;

extracting a sample of biological fluid from the patient;

contacting the opening of the sample element with the sample, such that a portion of the sample is drawn into the sample element;

transporting the sample portion from the opening to the sample cell through the supply passage via capillary action;

transmitting a calibration beam of radiation from the source through the sample element, but not through the sample portion, such that a calibration signal is generated by the optical detection system, the sample element having a first window separation where the calibration beam passes through the sample element;

transmitting an analyte beam of radiation from the source through the sample element and through the sample portion, such that an analyte signal is generated by the optical detection system, the sample element having a second window separation where the calibration beam passes through the sample element, the second window separation being different from the first window separation; and

correcting the analyte signal using the calibration signal to substantially eliminate the absorption of the sample element.

For example, the Neufeld patent teaches only a densitometer cell (FIGS. 3-5) with windows 82, 84 made of sapphire or calcium fluoride. (Neufeld, col. 5, ll. 40-52.) In addition, Neufeld's "calibrate operation" requires measurement of an additional blood sample, increasing the amount

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of blood withdrawn from the patient when performing a measurement. (Neufeld, col. 13, ll. 5-31.) For at least these reasons, Applicant respectfully submits that new Claim 95 is in condition for allowance over the prior art.

Supplemental Information Disclosure Statement

The present amendment paper is being filed via facsimile. Before the end of this week Applicant will submit via regular mail a Supplemental Information Disclosure Statement listing additional references for consideration by the Examiner.

Petition Under 37 C.F.R. § 1.48(a)

Applicant respectfully directs the Examiner's attention to the Petition Under 37 C.F.R. § 1.48(a), filed by Applicant in January 2004 and re-submitted in March 2004. Applicant's review of the USPTO's electronic records reveals no decision on this petition to date.

Conclusion

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although cancellations have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the cancellations are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, Mark J. Kertz at (949) 721-6318 to resolve such issue(s) promptly.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Oct. 4, 2004

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